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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,672	06/01/2001	Ryota Sugimoto	018961-054	8651
39083	7590	07/14/2004	EXAMINER	
THE KENEALY LAW OFFICE, L.L.C. 23 W. Myrtle St Alexandria, VA 22301			MATHEW, FENN C	
			ART UNIT	PAPER NUMBER
			3764	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,672

Applicant(s)

SUGIMOTO, RYOTA

Examiner

Fenn C Mathew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/15/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 5, 6, 10, 20, 32, 35-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Palmaz et al. (WO 99/23977). Referring to claim 1, Palmaz discloses an implantable tubular device having a deformable portion (400''') on a peripheral surface thereof, with the deformable portion forming a predetermined angle with respect to an axial direction of the device and inherently being easier to deform in comparison with the remainder of the device, the deformable portions being formed as grooves having a bottom surface provided on an outer surface of the tubular device.

3. Referring to claim 5, Palmaz teaches the grooves at various angles including in the range of 20-90 degree with the axial direction.

4. Referring to claim 6, Palmaz teaches the deformable portions are capable of continuously going around the periphery of the device.

5. Referring to claim 10, Palmaz teaches the device consisting of a stent.

6. Referring to claim 20, Palmaz teaches the device consisting of a stent having a frame structure, with the deformable portions on the frame structure.

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7. Referring to claim 32, Palmaz teaches an implantable tubular device comprising a plurality of annular members arranged in an axial direction of the device, and connection portions each connecteing the annular members to each other in the axial direction of the device, wherein each of the annular members has deformable portions forming a predetermined angle with respect to the axial direction of the device and being more easily deformed than a remainder of the device, the deformable portions being formed as grooves having a bottom surface provided on an outer surface of the tubular device.

8. Referring to claims 35-36, Palmaz teaches the grooves capable of having V-shaped bottom surfaces.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 4, 7, 9, 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz. Referring to claims 4, 9, and 13, Palmaz discloses the claimed invention with the exception of specific intervals and depths of the grooves. Palmaz does teach that the grooves can have a variety of acceptable groove depths and distances between grooves. The specific ranges claimed by the applicant are considered a matter of obvious design choice within the knowledge of the skilled artisan, as it appears the

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skilled artisan would choose appropriate specifications based on suitability for the intended use. Referring to claim 7, the feature of having the deformable portions be aligned in a spiral shape is also considered a matter of design choice.

11. Referring to claims 11-12, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore this limitation has not been given patentable weight. The skilled artisan would choose a manner in which to form the device based on suitability and desired results.

12. Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz in view of Alt et al. Referring to claim 14, Palmaz discloses the claimed invention except for the device carrying a medicine. Alt teaches that it is well known and advantageous to provide a medicinal coating to stents (column 8). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the stent of Palmaz with a medicinal coating as taught by Alt in order to deliver medicine to areas of the body once the device has been implanted.

13. Referring to claim 15, Palmaz discloses the claimed invention except for having at least one part of the outer surface coated with a coating material made of a biodegradable material. Alt teaches a coating comprising a biodegradable material (col. 6, lines 59-64), which can be used for a stent (col. 6, line 1). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Palmaz with the coating taught by Alt in order to provide a more biocompatible implant that will not cause harm during degradation.

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14. Referring to claim 16, Palmaz discloses the claimed invention except for having at least one part of the outer surface of the deformable portion coated with a coating material made of a biodegradable material. Alt teaches a coating comprising a biodegradable material (col. 6, lines 59-64), which can be used for a stent (col. 6, line 1). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the outer surface of the deformable portion of the device disclosed by Palmaz with the coating taught by Alt in order to provide a more biocompatible implant that will not cause harm during degradation.

15. Referring to claim 17, Palmaz as modified above discloses the coating carrying a medicine (col. 8).

16. Referring to claim 18, Palmaz, as modified by Alt discloses a coating material formed of a biodegradable material to which a medicine is added (col. 8).

17. Referring to claim 19, Palmaz as modified by Alt teaches an antibiotic.

18. Claims 2, 21-25, 33, 34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley in view of Palmaz. Referring to claim 2 and 22, Shanley discloses an implantable tubular device having a diameter so that the device can be inserted into a lumen, the device comprising a plurality of wavy annular member each formed of a wavy element and arranged in an axial direction (see fig. 12a), connection portions (84) connecting the wavy annular members to each other in an axial direction of the device, wherein each of the wavy annular members have free bent portions (118, 122) not connected to other wavy annular members, a deformable portion (40) inherently forming a predetermined angle with respect to the axial direction of the

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device. Shanley fails to teach deformable portions as substantially claimed. Palmaz teaches that it is desirable to have grooves on the stent, inherently defining deformable portions. Furthermore, Palmaz discloses that it is desirable to have deformable portions at any portion of the stent. Therefore, as it would have been obvious to one having ordinary skill in the art at the time of invention to provide the stent, including the wavy annular portions and free bent portions of Shanley with grooves as taught by Palmaz in order to aid in migration of cells.

19. Referring to claim 21, the modified Shanley teaches the device consisting of a stent having a frame structure, with the deformable portions on the frame structure.

20. Referring to claim 23-25 the modified Shanley discloses the claimed invention with the exception of specific intervals and depths of the grooves. The modified Shanley does teach that the grooves can have a variety of acceptable groove depths and distances between grooves. The specific ranges claimed by the applicant are considered a matter of obvious design choice within the knowledge of the skilled artisan, as it appears the skilled artisan would choose appropriate specifications based on suitability for the intended use. Referring to claim 25, the feature of having the deformable portions be aligned in a spiral shape is also considered a matter of design choice.

21. Referring to claim 26, the method of forming is not germane to the patentability of the apparatus. The limitation has been given no patentable weight. See discussion above.

22. Referring to claim 33 and 37, please refer to the above paragraphs.

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23. Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley in view of Palmaz, and further in view of Alt et al. Please refer to paragraphs 12-17 above.

Response to Arguments

24. Applicant's arguments with respect to claims 1-37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn C Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 12, 2004



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